

REMARKS

The pending Office Action addresses and rejects claims 1-26, 29-40, 42-48, 50-52, and 54-63. Applicants respectfully request reconsideration and allowance based on the remarks submitted herewith.

Amendments to the Claims

Applicants amend claims 17-20, 22, 50-52, and 55 to clarify that the recited shaft is the shaft of the installation tool. Claim 24 is amended to recite that the cannulated drive assembly slides along a second shaft connected to said expandable body. Claim 58 is amended to recite that the installation tool includes a trigger for inducing the driving of the expander pin. Claim 59 is amended to recite that the installation tool comprises a slap hammer. Claims 56 and 57 are canceled. Support for these amendments can be found throughout the original specification and figures, including at paragraphs [0064]-[0066], [0077]-[0079], [0086], and [0087] and FIGS. 1-8 and 17-30 of the published application. No new matter is added.

Rejections Pursuant to 35 U.S.C. § 112

The Examiner rejects claims 56-59 pursuant to 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner argues that the specification does not disclose a system having two insertion instruments – the installation tool recited in claim 29 and the cannulated driver assembly that was recited in claims 56-59. Claims 56 and 57 have been canceled and claims 58 and 59 no longer recite a cannulated driver assembly. Accordingly, the basis for this rejection is obviated.

The Examiner rejects claims 17-20, 22, 24, 50-52, 55, and 57 pursuant to 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner argues that references to the term “shaft” in these claims are unclear because both the installation tool and the expander pin have a “shaft.” Claims 17-20, 22, 50-52, and 55 are amended to recite that the shaft is the shaft of the installation tool. Claim 24 is amended to recite “a second shaft” instead of just “a shaft.” The recited second shaft is connected to the expandable body and is not the shaft of the expander pin recited in claim 1. Claim 57 is

canceled. Accordingly, the bases for these rejections pursuant to 35 U.S.C. § 112, second paragraph are obviated.

Rejections Pursuant to 35 U.S.C. § 103

U.S. Patent No. 7,074,203 of Johanson et al. in view of U.S. Patent No. 5,522,817 of Sander et al.

The Examiner rejects claims 1-5, 7, 11-17, 19-26, 29-33, 35, 39, 40, 42-48, 50, 52, 54-59, and 60-63 as being obvious over U.S. Patent No. 7,074,203 of Johanson et al. ("Johanson") in view of U.S. Patent No. 5,522,817 of Sander et al. ("Sander"). Claims 1 and 29 are independent and claims 2-5, 7, 11-17, 19-26, 30-33, 35, 39, 40, 42-48, 50, 52, 54, 55, 58, 59, and 60-63 depend therefrom. Claims 56 and 57 have been canceled. With respect to the independent claims, the Examiner argues that Johanson discloses the claimed invention except for an expandable body having a distal tip member and a proximal main member, and other recitations related to the distal tip and proximal main members (e.g., the distal tip member being of harder material than the proximal main member as recited in claim 1 and the distal tip member and the proximal main member being separable from one another in claim 29). The Examiner relies on Sander to remedy the deficiencies of Johanson. With respect to both claims 1 and 29, the Examiner argues that it would have been obvious to modify the device of Johanson in view of Sander for the purpose of enabling the expandable body to be drilled or driven directly into bone or other hard tissue without destroying the bioabsorbable proximal main member. Applicants disagree.

Johanson discloses deploying an expandable sleeve (4) into a bone hole by first forming a hole (37) in the location of the bone (39) and then deploying the expandable sleeve in the hole. (*See* col. 5, line 41 to col. 6, line 12.) The bone hole (37) is pre-drilled. While the Examiner argues that it would have been obvious to modify the expandable sleeve (4) to include a separable distal tip member being made of a harder material than a proximal main member and being tapered to enable the expandable sleeve to be drilled or driven directly into bone or other hard tissue, *there is no support for the Examiner's rationale*. The Examiner's proposed modification both renders the Johanson device unsatisfactory for its intended purposes and goes against the specific teachings of Johanson. Thus, there is no motivation to make the Examiner's propose modification. (*See* MPEP § 2143.01(V) and MPEP § 2145(X)(2), citations omitted.)

Neither Johanson nor Sander indicates that it is desirable to drill or drive an expandable sleeve into bone or other hard tissue instead of deploying it in a pre-formed hole. In fact, *Johanson was specifically designed to avoid such a configuration.*

Johanson explains that an object of its invention “is to provide such anchors, methods and devices that can be deployed easily *and without application of unnecessary leverage or counterforces.*” (Col. 2, lines 4-6, emphasis added.) In order to achieve this objective, Johanson is designed such that “the counterforce which a surgeon must impart to the apparatus during bone anchor deployment *is eliminated.*” (Col. 2, lines 55-60, emphasis added.) More particularly, while the rivet (6) of Johanson does impart a force on the expandable sleeve (4) to move the sleeve into the pre-formed hole (37), the Johanson device is specifically designed so that such deployment “has little or no effect on the bone. That is, the downward force applied to rivet 6 is not significantly imparted to bone 39 because rivet 6 moves within housing 2 and sleeve 4, both of which are held in place by tube 27. As a result, bone 39 moves little during initial deployment of rivet 6.” (Col. 6, lines 19-26.)

In view of these teachings of Johanson, no person having ordinary skill in the art would be motivated to make the Examiner’s proposed modification “for the purpose of enabling the expandable body to be drilled or driven directly into bone or other hard tissue.” Johanson specifically teaches deploying its expandable sleeve (4) into a *pre-formed* hole (37) *to avoid* imparting a drilling or driving force on the bone. Thus, the Examiner’s proposed modification would both circumvent the intended purpose of Johanson, and would be completely contrary to the teachings of Johanson. When a proposed modification renders the prior art invention being modified unsatisfactory for its intended purpose, or goes against the specific teachings of the prior art reference, there can be no motivation to make the proposed modification. (*See* MPEP § 2143.01(V) and MPEP § 2145(X)(2), citations omitted.)

Accordingly, claims 1 and 29, as well as claims 2-5, 7, 11-17, 19-26, 30-33, 35, 39, 40, 42-48, 50, 52, 54, 55, 58, 59, and 60-63 which depend therefrom, distinguish over Johanson in view of Sander and represents allowable subject matter.

Johanson et in view of Sander, further in view of U.S. Patent No. 6,123,711 of Winters

The Examiner rejects claims 6 and 34 as being obvious over Johanson in view of Sander, further in view of U.S. Patent No. 6,123,711 of Winters ("Winters"). Claims 6 and 34 depend from allowable base claims 1 and 29. At least because claims 6 and 34 depend from allowable base claims, they also represent allowable subject matter. The teachings of Winters, which the Examiner relies on to disclose a tissue attachment member having at least one laterally extending projection having a linear outer edge, fail to remedy the deficiencies of the combination of Johanson and Sander. Accordingly, claims 6 and 34 are allowable.

Johanson et in view of Sander, further in view of U.S. Patent No. 5,725,529 of Nicholson et al.

The Examiner rejects claims 8-10 and 36-38 as being obvious over Johanson in view of Sander, further in view of U.S. Patent No. 5,725,529 of Nicholson et al. ("Nicholson"). Claims 8-10 and 36-38 depend from allowable base claims 1 and 29. At least because claims 8-10 and 36-38 depend from allowable base claims, they also represent allowable subject matter. The teachings of Nicholson, which the Examiner relies on to disclose a suture being received in the bore formed in the expander pin and a second suture extending through a bore in the expander pin, fail to remedy the deficiencies of the combination of Johanson and Sander. Accordingly, claims 8-10 and 36-38 are allowable.

Johanson et in view of Sander, further in view of U.S. Patent No. 5,489,210 of Hanosh

The Examiner rejects claims 18 and 51 as being obvious over Johanson in view of Sander, further in view of U.S. Patent No. 5,489,210 of Hanosh ("Hanosh"). Claims 18 and 51 depend from allowable base claims 1 and 29. At least because claims 18 and 51 depend from allowable base claims, they also represent allowable subject matter. The teachings of Hanosh, which the Examiner relies on to disclose a shaft and an expandable body being threadingly interengageable with one another, fail to remedy the deficiencies of the combination of Johanson and Sander. Accordingly, claims 18 and 51 are allowable.

Double Patenting

The Examiner rejects claims 1-63 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-78 of U.S. Patent No. 6,733,506 in view of Sander. Applicants note that claims 27, 28, 41, 49, 53, 56, and 57 have been canceled. Applicants reserve the right to submit a Terminal Disclaimer with respect to the term of U.S. Patent No. 6,733,506 in the event that the Examiner maintains this rejection once patentable subject matter has been agreed upon.

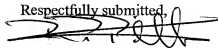
Conclusion

All pending claims are believed to be in condition for allowance. If the Examiner believes that an interview would facilitate the resolution of any outstanding issues, he is kindly requested to contact the undersigned.

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Respectfully submitted,



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